JUN 27 2014

510(k) Summary

Submitter Information

Applicant/Sponsor: NovoSource, Inc.
714 E Monument Ave, Suite 220
Dayton, OH 45402

Contact Person: Allison Scott, RAC
317-228-8719
Allison.Scott@Navigant.com

Date of Preparation: June 27, 2014

Trade Name: NovoHip Vitamin E liner

Common Name: Hip prosthesis

Classification Name(s): Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis + Additive porous uncemented per 21 CFR 888.3358

Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358

Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353

Device Produce Code(s): OQG, LPH, LZO

Predicate Devices: NovoHip Total Hip System (K132158)

Zimmer Vivacit-E Vitamin E Highly Crosslinked Polyethylene Liners (K120370)

DePuy Pinnacle Acetabular System (K001534)

Wright Medical Lineage Acetabular System (K002149)

Device Description

The NovoHip Total Hip System is a non-cemented hip prosthesis that consists of a 4-part total hip replacement system including femoral stem, femoral head, acetabular liner, and acetabular shell components. The femoral head component articulates within the poly acetabular component. The acetabular liner snaps into the acetabular shell component. The design and sizing of the components correspond to natural hip anatomy to restore normal rotation, extension, and flexion.

The NovoHip Vitamin E liners are components to be used with the NovoHip Total Hip System, previously cleared via K132158. The Vitamin E poly acetabular component snaps into the metal acetabular components that were previously cleared with the NovoHip Total Hip System.

Intended Use(s)

NovoHip Vitamin E liners are intended for use with the NovoSource NovoHip Total Hip System. NovoSource hip implant components are indicated for use in cementless reconstruction of the articulating surface of femoral and/or acetabular portions of the hip that are severely disabled and/or very painful as a result of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis or traumatic arthritis
- Correction of functional deformity
- Non-union femoral neck fracture
- Trochanteric fractures of the proximal femur with head involvement which is unmanageable using other techniques.

The components can be used for primary hip arthroplasty or for revision of a failed total hip arthroplasty.

Technological Characteristics

The NovoHip Total Hip System and NovoHip Vitamin E liner have the same intended use as the predicate devices. The NovoHip Total Hip System and NovoHip Vitamin-E liner have similar indications for use as the predicate devices. The NovoHip Vitamin E liner is manufactured from the same materials as the predicate devices. The range of sizes of the NovoHip Vitamin E liner is similar to the predicate devices.

Non-Clinical Performance Data Summary

1. Thermal Properties (DSC) Test
2. Small Punch Testing
3. Oxidation Index Analysis
4. Density Testing
5. Trans-Vinylene Yield Index Analysis
6. In Situ Determination of Network Parameters
7. Tensile Property Test
8. Izod Impact Test
9. Residual Free Radical Content
10. Compressive Modulus
11. Fatigue Crack Propagation
12. Poisson's Ratio
13. Exhaustive Extraction
14. Consolidation Assessment
15. Post-Wear Analysis
16. Fatigue Crack Propagation
17. Analysis of Extraction Residue
18. Orbital Hip Wear
19. Wear Particle Analysis at 1,000,000 Cycles
20. Locking Mechanism Strength Evaluation
21. Lever-Out Test
22. Torque-Out Test
23. Push-In Test
24. Push-Out Test
25. Rotational Stability Test
26. Torsional Strength of Metallic Bone Screws
27. Driving Torque of Metallic Bone Screws
28. Axial Pullout Strength of Metallic Bone Screws

Clinical Performance Data Summary

No clinical testing was required.

Non-Clinical and Clinical Performance Data Conclusions

Based on testing results and the comparisons provided, the NovoHip Vitamin E liner is considered substantially equivalent to the Zimmer Vivacit-E Vitamin E Highly Crosslinked Polyethylene Liners, DePuy Pinnacle Acetabular System, and Wright Medical Lineage Acetabular System in material, construction, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

NovoSource, Incorporated
Navigant Consulting, Incorporated
% Allison Scott, RAC
Senior Consultant
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K140701
Trade/Device Name: NovoHip Vitamin E Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, LPH, LZO
Dated: May 27, 2014
Received: May 28, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140701 (pg 1/1)

Device Name
NovoSource NovoHip Total Hip System

Indications for Use *(Describe)*

NovoHip Vitamin E liners are intended for use with the NovoSource NovoHip Total Hip System. NovoSource hip implant components are indicated for use in cementless reconstruction of the articulating surface of femoral and/or acetabular portions of the hip that are severely disabled and/or very painful as a result of:

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The components can be used for primary hip arthroplasty or for revision of a failed total hip arthroplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Elizabeth D. Frank -S

Division of Orthopedic Devices

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